Abbott

News Release

Abbott Initiates Voluntarily Recall of Specific Lots of Three Coronary Catheters

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ABBOTT PARK, Ill., May 12, 2017 — Abbott has initiated a voluntary recall of specific lots of three catheters: NC Trek RX Coronary Dilatation Catheter, NC Traveler Coronary Dilatation Catheter, and NC Tenku RX PTCA Balloon Catheter.

This recall does not affect patients who have successfully undergone cardiac procedures using these devices. Abbott has already implemented corrective actions to ensure the products perform as intended.

Products from the identified lots may exhibit difficulty in removing the protective balloon sheath, which could cause problems with inflating or deflating the balloon. Potential risks associated with balloon inflation and deflation difficulties include air embolism, additional intervention, thrombosis, and myocardial infarction. In one reported case, failure to deflate the balloon necessitated surgery, which resulted in multiple post-surgical complications leading to death. The FDA has classified this as a Class I recall, where exposure to a device presents a reasonable likelihood of serious adverse health consequences or death. The cumulative frequency of reported events in difficulty of removing the sheath, and inflation and deflation of the balloon, is 0.12 percent worldwide.

Abbott began contacting customers in March who received coronary catheters from the affected lots, and is arranging the return and replacement of all remaining products. The total number of distributed units from identified lots potentially affected is 449,661. Global Health Authorities have been notified of the voluntary recall.

Specific lots of affected product were manufactured between Jan. 1, 2015 – Jan. 2, 2017, and were distributed between Jan. 13, 2015 – March 14, 2017. For more information, please see Abbott's field safety notice.

For Important Safety Information on NC Trek Catheters visit: https://www.vascular.abbott/content/dam/bss/divisionalsites/av/products/AP2936324_NC_Trek_RX_OTW_WIPCA.pdf

Consumers with questions may contact the company via telephone at (800) 227-9902 between the hours of 5 a.m. and 5 p.m. PST.

Adverse reactions or quality problems experienced with the use of this device may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

•Complete and submit the report online: www.fda.gov/medwatch/report.htm.

•Regular mail or fax: Download form http://www.fda.gov/MedWatch/getforms.htm or call +1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to +1-800-FDA-0178.

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